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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,328	01/23/2004	Charles D. Boyd	PXE-001C1	6535
22832 7590 07/19/2007 Kirkpatrick & Lockhart Preston Gates Ellis LLP (FORMERLY KIRKPATRICK & LOCKHART NICHOLSON GRAHAM) STATE STREET FINANCIAL CENTER One Lincoln Street BOSTON, MA 02111-2950			EXAMINER WILDER, CYNTHIA B	
			ART UNIT 1637	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/764,328

Applicant(s)

BOYD ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-64, 67-70, 73, 79 and 80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-64, 67-70, 73, 79, 80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 4/27/2007 is acknowledged. Claims 1-33 and 71-72 have been canceled. Claims 65-66 and 74-78 have been withdrawn. Claims 79-80 have been added. Claims 34-64, 67-70, 73, and 79-80 are pending. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejection

3. The objection to the specification is withdrawn in view of Applicant's amendment to the specification. The claim rejection under 35 USC 112 first paragraph as lacking adequate written description is withdrawn in view of Applicant's arguments and upon further review of Applicant's specification. The claim rejection under 35 USC 112 first paragraph as lacking enablement is maintained and discussed below. The double patenting rejection is maintained and discussed below.

Claim Rejection 35 U.S.C. 112: Enablement Rejection

4. Once again, claims 34-63, 67-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for screening for the presence of a PXE mutation comprising, interrogating an MRP6 nucleic acid in patient sample for the presence of a mutation, wherein the mutation is a mutation at

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codon 1141, it does not reasonably provide enablement for a method for detecting any PXE mutation in a patient comprising, interrogating an MRP6 nucleic acid in a patient sample for the presence of any mutation or any PXE mutation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The first paragraph of section 112 requires the specification describe how to make and use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support determination that a disclosure does not satisfy the enablement requirements and whether any necessary experimentation is "undue". These factors include but are not limited to: (1) quantity of experimentation necessary, (2) the amount of direction or guidance presented in the specification, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of the unpredictability of the art and (8) the breadth of the claims. (See *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404, (Fed. Cir. 1988)) (*MPEP 2164.01(a)*).

The claims of the instant invention are broadly drawn to a method for detecting any PXE mutation in a patient by establishing if any mutation in an MRP6 gene is associated with PXE; a method for identifying a patient at risk of having children with PXE comprising interrogating an MRP6 nucleic acid in a patient sample for the presence of any MRP6 allele; a method for identifying a patient at risk of developing a PXE associated symptom comprising interrogating an MRP6 nucleic acid in a patient

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sample for the presence of any MRP6 allele and a method for diagnosing PXE in a patient comprising interrogating an MRP6 nucleic acid in a patient sample for the presence of any pair of two MRP6 alleles.

The specification teaches the sequence of the MRP6 gene, which spans 31 exons (SEQ ID NO: 1) and identifies several unrelated PXE mutations at for example e.g., base 3775 and codon 1141 (see Tables 1 and 2). These mutations are located in different exons of the MRP6 gene. The specification suggests that the MRP6 gene is associated to PXE mutations and thereby postulates that mutations in the MRP6 gene or the presence of any pair of two alleles may be correlated with detection of PXE. However, the specification does not provide any evidence of an association between the MRP6 nucleic acid and any mutation of PXE. Case law has established that "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'". *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "[t]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the *Court in Genetech Inc. v. Novo Nordisk* 42 USPQ2d 1001 held that "[I]t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement".

In the instant case, the claims are not commensurate in scope with the enabling disclosure because the claims are inclusive of methods for detecting a PXE mutation, method of identifying a patient's risk of having children with PXE and a method of diagnosing PXE in a patient by detecting the presence of any mutation or allele or pair of two alleles in an MRP6 nucleic acid. The specification, at best, teaches several unrelated members of the broadly claimed genus of MRP6 nucleic acids comprising PXE mutations that have been identified by their complete structure, i.e., codon 1141. The broadest reasonable interpretation of the claims indicates that the claims are inclusive to a large genus of mutations or alleles present at any position on the MRP6 gene, including the promoter, 3' and 5' untranslated regions, exon and intron regions of the MRP6 gene. It is noted that the dependent claims 43-48 recited therein limit the mutations to non-conserved amino acid substitution, splice site in an intron, the promoter region, a polyA site, in an exon or exons 1-31 of the MRP6 gene. However, the specification does not teach any mutations that are non-conserved amino acid substitutions, mutations that are located in splice sites of introns, mutations that are located in the promoter region of the MRP6 gene, mutations that are located in the polyA region of the MRP6 gene, nor does the specification exemplify mutations that are located in exons 1-23, 25, 26 and 29-31. The specification only teaches for examples some mutations in exons 8, 12, 13, 16, 18, 23-30 as shown in Table 1 and *exemplify* by example three mutations in exon 24 (codon 1114, 1138 and 1141), one mutation in exon 27 (base 3775), and five mutations in exon 28 (1298, 1302, 1303, 1314, 1321) of the MRP6 gene as being associated with PXE (see page 46-47 and Fig 2 which clearly

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show an association of mutations at codon, 1114, 1138, 1141, 1259, 1298, 1302, 1303, 1314, 1321 and base 3775 being associated with PXE). While one could contemplate a nucleotide substitution at each and every position in the MRP6 gene, such substitutions are not considered to equivalent to PXE mutations. Rather, mutations in the MRP6 gene associated with PXE mutations represents a distinct group of nucleotide variations which are expected to occur at only specific locations within the gene and consist of specific nucleotide alterations. In order for one of ordinary skill in the art to make and use this distinct group of nucleotide variations, one would have to test hundreds, if not thousands, of possible nucleotide alterations throughout the MRP6 gene that are PXE mutations. Thus, undue experimentation is deemed necessary to practice the instant invention commensurate fully in scope.

As to the level of unpredictability in the art concerning the instant invention, the specification teaches that one of these mutations, R1141X, which is the mutation at codon 1141, is "far more likely to be found in the general population than private mutations". (PG. 51, line 21-22), and "that two single-allele mutations (R1141X, R1339C) were found in control panels of normal individuals indicating that that heterozygote mutant (MRP6) ABCC6 alleles can be found in the normal population" (page 9, lines 20-23). These passages support the unpredictability regarding "mutations or alleles" shown be associates with PXE and their uses for diagnosis or identification of PXE. These passages further suggest that it is highly unpredictable that determining any mutation in MRP6 can be considered a mutation shown to be associates with PXE.

Therefore, in view of the high level of unpredictability in the art and in view of the lack of disclosure regarding the plethora of possible PXE mutations, undue experimentation would be required to practice the invention as broadly written.

Applicant's traversal

5. Applicant traverses the rejection on the following ground: Applicant summarizes the Examiner's rejection and states that the present specification fully enables one of skill in the art to determine if a mutation in a MRP6 gene is a co-segregator with a PXE phenotype as recited in the independent claims 34 and 63. Applicant states that the specification provides reasonable guidance or direction on how to practice the claimed invention. Applicant states that for example, the specification teaches a variety of methods for detecting mutations in the MRP6 gene and teaches methods to determine if the mutation is a co-segregator with a PXE phenotype using multi-generational pedigree analysis. Applicant states that one skill in the art upon review of the recited paragraphs would readily have understood how to carry out nucleic acid assay and co-segregation analysis in order to determine if a mutation in an MRP6 gene co-segregates with a PXE phenotype. Applicant states that the present invention fully enables one of skill in the art to determine a mutation, abnormal presence or absence of at least one nucleic acid fragment or sequence in a patient's MRP6 gene compared to a normal control as recited in the independent claims 67, 68, 79 and 80. Applicant states that the specification provides reasonable guidance or direction on how to practice the claimed invention. Applicant cites paragraphs from the instant specification and states that one of skill in the art upon review of the recited paragraphs would readily have understood

how to carry out nucleic acid assays and to compare the assay results to a normal control in order to determine a mutation, abnormal presence or absence of at least one nucleic acid fragment or sequence, in the MRP6 gene. Applicant asserts that secondly, all methods needed to detect abnormal presence or absence of a nucleic acid fragment or sequence in the MRP6 gene were well known in the art when this application was filed, it was routine for one of ordinary skill in the art to isolate nucleic acids from a patient sample, to conduct a nucleic acid assay such as hybridization or sequencing, to determine nucleic acid or protein fragment patterns or sequences and to compare the determined patterns or sequences to normal controls in order to detect a presence or absence of abnormal fragments or sequence. Applicant further submits that experimentation, particularly when routine and thoroughly disclosed is permissible. Applicant states that the experimentation necessary to practice the invention is not undue and submit that in view of the teachings of the present application and armed with the knowledge available in the art, one of ordinary skill readily would have been able to detect a PXE mutations in a patient by establishing a mutation in an MRP6 gene is associates with PXE by determining if a mutation is a co-segregator with a PXE phenotype and to detect a patient who is more likely to develop PXE than a normal patient by determining abnormal present or absence of at least one nucleic acid fragment or sequence in the patient's MRP6 gene compared to normal control. Applicant submit that the knowledge of a specific mutation in the MRP6 gene is not required to practice the invention as recited in the amended and independent claims. Applicant states that detection of a mutation manifested by at least one abnormal

nucleic acid fragment or sequence in a patient's MRP6 gene would be sufficient to indicate that the patient is more likely to develop PXE than a normal patient because an MRP6 gene containing an abnormal nucleic acid fragment or sequence is more likely to have an abnormal MRP6 protein compared to a normal MRP6 gene. Applicant states that similar correlation between defects in genes without knowledge of specific mutations and disease is known in the medical arts. Applicant concludes for all the reasons discussed above, reconsideration and withdrawal of the rejection is requested.

Examiner's Response

6. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: The Examiner acknowledges Applicant's arguments but respectfully disagree that the rejected claims are enabled as currently written. In regards to Applicant arguments that the instant invention is limited by the teaching that the MRP6 mutation co-segregates with a PXE phenotype and hence enabling, the Examiner respectfully disagree because post dated art by Hu et al (Investigative Ophthalmology, vol. 44, no. 5, pages 1824-1829, May 2203) support the unpredictability of using phenotypic data from the genotype data as a means of determining the presence of PXE (see page 1829, col. 1, section entitled "Features of the Phenotype").. Hu et al expressly teach that clinical variability in PXE has been demonstrated previously and also occurred in their R1141X patient cohort. Hu teaches that in their study, they could not firmly predict the phenotype from the genotype or vice versa. Applicant states that the correlation between genotype and phenotype may be obscured by several factors. Hu et al state that the small size of their cohort limited the

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evaluation of the genotype and phenotype correlation. Hu et al additionally state that in addition, additional unknown environmental, metabolic or genetic determinants may modify the phenotype (page 1829). Hu et al concludes by stating that in future studies, we have to investigate the PXE phenotype in a thorough prospective way to obtain any significant clues for genotype-phenotype relationships".

Phendner et al., (J. Med. Genet. Online, 2007 Jul 6; [Epub ahead of print], pages 1-16), support the teaching of Hu et al and state that "finding no genotype-phenotype correlation in complex Mendelian disorders, such as metabolic diseases, is not uncommon. Phendner et al teach that "this lack of association suggest that no simple relationship exists between the type and mutations, the mutations themselves and the actual severity of disease. (page 12, second paragraph). Phendner et al further states that because of the significant clinical relevance, further work is needed to determine if there are subcellular phenotypes that correlate with genotypes in PXE (page 12, last paragraph).

Given the unpredictability in art for using genotypic-phenotypic data as a means of detecting PXE, it is also unpredictable that detecting co-segregation of a mutation with a PXE phenotype is indicative of a patient having PXE as claimed in the instant invention. Likewise, given the fact that the instant invention broadly encompasses any mutation in the MRP6 gene, it is also unpredictable any mutation present in the MRP6 gene along with phenotypic data will result in accurately detecting a patient having PXE. The examiner maintains that the instant invention is not fully enabled in scope.

Applicant's arguments are not sufficient to overcome the claimed rejection. Accordingly, the rejection under 35 USC 112 first paragraph is maintained.

Double Patenting

7. Once again, claims 34-64 and 67-73 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6780587 B2.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the instant invention and the claims 1-10 of US Patent 6,780,587 are drawn to a method for screening a patient for the presence of a PXE mutation. The claims of US Patent 6,780,587 only differs from the claims 34-64 and 67-73 in that the claim of US Patent '587 identifies wherein the mutation is selected from the group consisting of a mutation at codon, 1114, 1138, 1141, 1259, 1298, 1302, 1303, 1314 and 1321, whereas the claims of the instant invention either broadly encompasses any PXE mutation The claims only differ in that the claims 34-63, 67-72

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of the instant invention are broader in scope and encompasses any PXE mutation and the claims 64 and 73 are limited to a mutation at codon 1141.

Thus, the claims 34-64 and 67-73 of the instant invention falls entirely within the scope of the claims 1-10 of US patent 6,780,587. As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), "a second application-- "containing a broader claim, more generical in its character than the specific claim in the prior patent"-typically cannot support an independent valid patent. *Miller*, 151, U.S. at 198; See *Stanley*, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., *Titanium metal corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

Applicant's Traversal and Examiner's Response

8. Applicant traverses the rejection on the following grounds: Applicant states that a Terminal Disclaimer will be presented once one or more claims are found allowable. Applicant concludes that the filing a Terminal Disclaimer will obviate the double patenting rejection.

9. All of the arguments have been thoroughly reviewed and considered but are not found persuasive because a Terminal Disclaimer (TD) has not been filed in the instant

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invention. Additionally, since the claims are not found to be in condition for allowance, and a TD has not been filed, the rejection is maintained (see MPEP 804).

New Grounds of Rejections

THE NEW GROUNDS OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 79-80 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6780587 B2.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably

distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the instant invention and the claims 1-10 of US Patent 6,780,587 are drawn to a method for screening a patient for the presence of a PXE mutation. The claims of US Patent 6,780,587 only differs from the claims 34-64 and 67-73 in that the claim of US Patent '587 identifies wherein the mutation is selected from the group consisting of a mutation at codon, 1114, 1138, 1141, 1259, 1298, 1302, 1303, 1314 and 1321, whereas the claims of the instant invention either broadly encompasses any PXE mutation The claims only differ in that the claims 79-80 of the instant invention are broader in scope and encompasses any MRP6 mutation.

Thus, the claims 79-80 of the instant invention falls entirely within the scope of the claims 1-10 of US patent 6,780,587. As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), "a second application-- "containing a broader claim, more generic in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. *Miller*, 151, U.S. at 198; See *Stanley*, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., *Titanium metal corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer,

the species claims preclude issuance of the generical application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

Conclusion

12. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

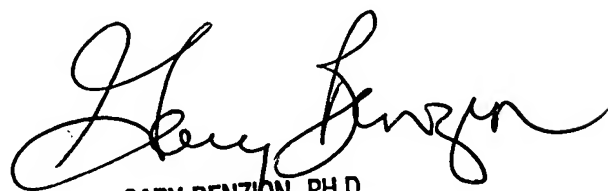
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cbw



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